

## REMARKS

This Response and Amendment is in response to the Office Action mailed on June 3, 2003. Reconsideration of this application is respectfully requested.

### Claim Amendments

Applicants submit that the claim amendments are fully supported by the elected claims, the specification and the drawings. Further, Applicants submit that new Claims 27-41 are fully supported by the elected claims, the specification and the drawings, and are readable on the elected species. No new matter has been added.

### Election / Restriction

Applicants affirm the election of Claims 7-13 and 16-24 made by the undersigned attorney on May 28, 2003. Consequently, Applicants have canceled Claims 1-6, 14, 15, 25 and 26 as being drawn to a non-elected invention. Applicants intend and specifically reserve the right to file Claims 1-6, 14, 15, 25 and 26 in one or more continuing applications.

### Claim Rejections

1. The Office Action rejected Claims 7, 16 and 22 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,923,442 to Segall et al. ("the Segall patent"). This rejection is respectfully traversed.

Claims 7 and 16 specify, *inter alia*, a sensor operable to measure a signal resulting from the energy supplied to the tissue by the energy source, the signal being proportional

to the energy transformed, reflected, scattered or absorbed by an extravasated fluid present in the vicinity of the site.

The Segall patent is directed to a blood substitute suitable for replacing blood during surgical procedures at hypothermic temperatures, not to an apparatus or method for determining whether the blood substitute or other fluid has extravasated into tissue surrounding a fluid injection site.

While the Segall patent discloses in one passage that “dye may be included or introduced into the blood substitute at stages of surgery when it is desirable to check leakage of blood from surgically repaired blood vessels” (col. 3, lines 27-30), the Segall patent does not disclose or suggest any specific apparatus or method for detecting the blood leakage. For example, in comparison to the inventions of Claims 7 and 16, the Segall patent appears to be silent as to the energy source to interact with the dye that is included in the blood substitute and the sensor to measure a signal that is proportional to the energy transformed, reflected, scattered or absorbed by an extravasated fluid present in the vicinity of the site.

In addition, Applicants submit that further teachings of the Segall patent refute the premise that the Segall patent is directed to an extravasation detection device or system. Specifically, the Segal patent teaches that the “present invention is directed to a blood substitute that comprises . . . a macromolecular oncotic agent . . . . By oncotic agent is meant substances that are of a size that is not able to leave the circulation by traversing the fenestrations of the capillary bed.” (Col. 4, lines 40-42 and 61-64.) Further, “in each of these procedures [in which the blood substitute is used] the first solution is

administered after partial exsanguination of the subject patient or donor or is administered while progressively exsanguinating the patient or donor . . .” (Col. 7, lines 59-66.)

Based on the above passages and the overall teachings of the Segall patent, Applicants submit that the Segall patent teaches and contemplates a blood substitute that is specifically designed to replace blood and to remain within the circulatory system of a patient during the various hypothermic surgical procedures described therein. In fact, Applicants submit that the Segall patent contemplates that the blood substitute must remain within the circulatory system of the patient in order for the patient to survive the various hypothermic surgical procedures.

While the Segall patent may acknowledge in the passage in Column 3 thereof (cited above) that it is desirable to check for “leakage” of the blood substitute from blood vessels, Applicants submit that a statement of desirability, without a teaching specifying the structures, devices and/or methods for detecting the leakage, is not sufficient to anticipate or render obvious an invention providing those needed or enabling elements.

Likewise, Claim 22 specifies, *inter alia*, a contrast medium containing an additive adapted to affect a signal resulting from energy supplied to tissue in the vicinity of a site. In addition to the energy source, sensor and measured signals discussed above with respect to Claims 7 and 16, Applicants submit that the Segall patent does not disclose a contrast medium containing an additive that is adapted to affect the signal. For example, because the Segall patent does not specify the energy source or the sensor, Applicants submit that the Segall patent does not disclose or suggest that the blood substitute may be an ‘additive’ in a contrast medium that is adapted to affect the signal

and therefore can be used to detect the presence of extravasated contrast medium in the tissue.

For at least the above reasons, Applicants submit that the Segall patent does not disclose each and every element or limitation of Claims 7, 16 and 22, and that the rejection based thereon should be withdrawn.

2. The Office Action rejected Claims 17-13 and 16-22 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2002-0172323 to Karellas et al. (“the Karellas patent”). Applicants submit that this rejection is moot.

To remove the Karellas patent as a prior art reference, Applicants submit the accompanying Rule 131 Declaration executed by Chad Bouton, a named inventor of the present application. The Rule 131 Declaration and the evidentiary document submitted therewith, “Extravasation Phase 2 Final Report,” establishes a date of completion (at least as early as June 8, 1999) of the invention of Claims 7, 11, 16, 18 and 23 in this patent application, which is a date earlier than the earliest priority date (i.e., February 2, 2001) of the Karellas patent.<sup>1</sup>

3. The Office Action rejected Claim 11 under 35 U.S.C. § 103(a) as being unpatentable over the Segall patent. This rejection is respectfully traversed.

Claim 11 specifies, *inter alia*, an energy source to supply ultrasonic energy to tissue in the vicinity of a site, and a sensor to measure a signal resulting from the energy

---

<sup>1</sup> Applicants can and specifically reserve the right to prove an earlier invention date if necessary in future proceedings.

supplied to the tissue, the signal being proportional to the ultrasonic energy reflected, scattered or absorbed by an extravasated fluid present in the vicinity of the site.

As discussed above, the Segall patent does not disclose an energy source for supplying energy to tissue in the vicinity of a site, a sensor to measure a signal resulting from the energy, or that the signal is proportional to energy reflected, scattered or absorbed by an extravasated fluid present in the vicinity of the site. Absent one or more of those claimed elements in the Segall patent, Applicants submit that the Segall patent provides no motivation to a skilled artisan to include an ultrasonic energy source to arrive at the claimed invention.

For at least the above reasons, Applicants submit that the Segall patent does not provide or render obvious Applicants' invention of Claim 11, and that the rejection based thereon should be withdrawn.

4. The Office Action rejected Claims 8-10, 12, 13, 17-21, 23 and 24 under 35 U.S.C. § 103(a) as being unpatentable over the Segall patent in view of U.S. Patent No. 5,954,668 to Uber, III et al. ("the Uber patent"). This rejection is respectfully traversed.

As discussed above, the Segal patent does not disclose an energy source for supplying energy to tissue in the vicinity of a site, a sensor to measure a signal resulting from the energy, or that the signal is proportional to energy reflected, scattered or absorbed by an extravasated fluid present in the vicinity of the site.

The Uber patent likewise does not provide the required elements of Applicant's invention. Specifically, the Uber patent detects extravasation by sensing and comparing tissue and fluid temperature. The Office Action has not specified a motivation to

combine the temperature sensing technique of the Uber patent with the blood substitute of the Segal patent to arrive at Applicant's invention.

Even if the Segall patent disclosed or enabled an operable extravasation system or method including the claimed elements of Applicants' invention (which the Segall patent does not), Applicants submit that the extravasation system disclosed in the Uber patent would be widely redundant or incompatible with the teachings of the Segall patent.

For at least the above reasons, Applicants submit that the proposed combination of the Segall patent and the Uber patent does not provide or render obvious Applicants' inventions of Claims 8-10, 12, 13, 17-21, 23 and 24, and that the rejection based thereon should be withdrawn.

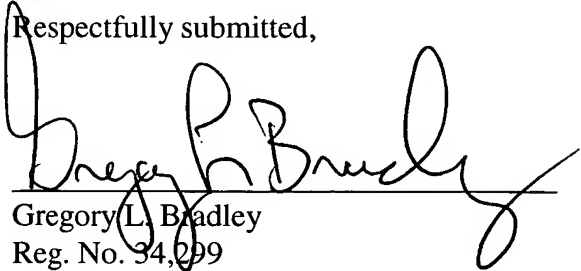
5. The Office Action rejected Claims 23 and 24 under 35 U.S.C. § 103(a) as being unpatentable over the Karellas patent. Applicants submit that this rejection is moot in view of the accompanying Rule 131 Declaration.

Conclusion

In view of the foregoing amendments and remarks, Applicants submit that the application is now in condition for allowance. Reconsideration of this application is respectfully requested.

Dated: October 3, 2003

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Gregory L. Bradley", written over a horizontal line.

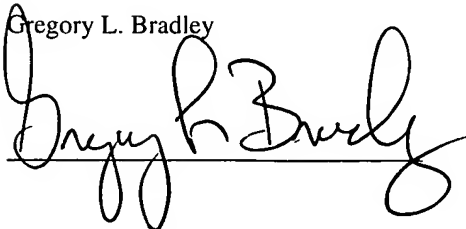
Gregory L. Bradley  
Reg. No. 34,299

Medrad, Inc.  
One Medrad Drive  
Indianola, PA 15051  
Telephone: (412) 767-2400 x3021

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on October 3, 2003, with sufficient postage as first-class mail in an envelope addressed to the: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Gregory L. Bradley

A handwritten signature in black ink, appearing to read "Gregory L. Bradley", written over a horizontal line.